

DIVERS-II: Treating depression in dialysis patients with a tailored eHealth cognitive based treatment: A cluster randomized controlled trial.

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An eHealth CBT intervention reduces depressive symptoms in dialysis patients.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29658

Bron

NTR

Verkorte titel

DIVERS-II (Internet Intervention)

Aandoening

Depressie / Depression / Depressive disorder

Dialyse / Dialysis / Renal replacement therapy

Nierfalen / Eindstadium nierfalen / Kidney failure / End stage renal disease

Ondersteuning

Primaire sponsor: OLVG Amsterdam

Overige ondersteuning: ZonMw projectnummer 843001804

OLVG WO 17.162

Stichting Zabawas

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Cluster randomized controlled trial of the intervention versus care as usual.
The primary outcome is the depression score, measured using the Beck Depression Inventory (BDI). The difference between T0 and T1 (1-2 weeks after treatment) is the primary outcome for clinical effectiveness. Care as usual will be compared with the intervention group.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

Depressive symptoms are highly prevalent in dialysis patients and associated with adverse outcomes. However, depression is underdiagnosed and undertreated in this population. There is lack of robust randomized controlled trials relating to the effectiveness of therapeutic interventions. This study aims to investigate the effectiveness of an eHealth self-help intervention for depressive symptoms in dialysis patients. Furthermore, the biochemical changes and associations involved in depression in dialysis patients are examined.

This study can provide an accessible, patient friendly, low-cost intervention for the treatment of depressive symptoms and improving quality of life of dialysis patients.

Primary objective:

To deliver an easy accessible, patient friendly and low-cost self-help intervention for the treatment of depressive symptoms in dialysis patients.

Main hypothesis:

An eHealth CBT intervention reduces depressive symptoms in dialysis patients.

Objective:

1. To investigate the effectiveness of a self-help CBT in lowering depressive symptoms and

the associated adverse outcomes.

2. To examine the biochemical mechanisms involved in treating depression.

Doel van het onderzoek

An eHealth CBT intervention reduces depressive symptoms in dialysis patients.

Onderzoeksopzet

T0: Baseline (before randomization)

T1: Within 1-2 weeks after the intervention

T2: 6 months

T3: 12 months

T4: 18 months

Onderzoeksproduct en/of interventie

Psychosocial intervention: Self-help cognitive based therapy, tailored for dialysis patients with build-in support from a psychotherapist. This treatment is based on a frequently used problem solving therapy. It is offered through both an e-health portal and on paper, depending on the preference of the patient. The intervention consists of 5 modules with explanatory texts and animations, exercises and weekly feedback from a trained psychotherapist.

Care-as-usual:

Care as usual as provided by nephrologist, social workers and if applicable psychotherapists. This group will receive an online infomodule about depression in end-stage-renal-disease.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- ≥ 18 years of age
- undergoing dialysis treatment for at least 90 days
- being able to complete a questionnaire in Dutch
- have a BDI depression score of 13 or higher (BDI = Beck Depression Inventory-II)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Suicidal thoughts (measured using a short screening survey)
- Participation in other psychotherapeutic trials

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-01-2018
Aantal proefpersonen:	206
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	13-11-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6648
NTR-old	NTR6834
Ander register	OLVG: WO 17.162 : METC: NL58520.100.17

Resultaten